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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/258,132	02/26/1999	PHILIP GOELET	04990.0007.U	3407

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09/20/2002

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EXAMINER

MYERS, CARLA J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 09/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/258,132

Applicant(s)

GOELET ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20 . 6) ☐ Other: _____

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1. The request filed on August 6, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/258,132 is acceptable and a CPA has been established. An action on the CPA follows.
2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821(e) which states that "(t)he computer readable form is a copy of the "Sequence Listing" and will not necessarily be retained as part of the patent application file. If the computer readable form of a new application is to be identical with the computer readable form of another application of the applicant on file in the Office, reference may be made to the other application and computer readable form in lieu of filing a duplicate computer readable form in the new application. The new application shall be accompanied by a letter making reference to the other application and computer readable form...". Accordingly, Applicant is required to submit a letter stating, for example:

The computer readable form in this application is identical with that filed in Application Number _____, filed _____. In accordance with 37 CFR 1.821(e), please use the (first-filed, last-filed or only, whichever is applicable) computer readable form filed in that application as the computer readable form in the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the Sequence Listing is

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(included in the originally-filed specification of the instant application, included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable).

Furthermore, Applicant is required to submit a paper copy of the Sequence Listing and a letter stating that the content of the paper and computer readable copies of the Sequence Listing are the same and, where applicable, include no new matter.

3. The terminal disclaimer filed on February 28, 2001 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 5,888,819 and 6,004,744 has been reviewed and is accepted. The terminal disclaimer has been recorded.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 60-63 are directed to a method in which either one or more unique oligonucleotide primers are attached to a unique affinity moiety which specifically binds to a discrete position on a solid support or a plurality of unique oligonucleotide primers are attached to discrete positions of

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a solid support and then the target nucleic acid is added and to form a duplex and extension occurs on the immobilized primers. Additionally, claim 63 further includes a step of sorting the extended primers by affinity capture. However, the specification does not provide support for these concepts.

Applicants point to page 27, lines 12-24, pages 29 and 30 and page 31, lines 25-35 as providing support for these new claims. Upon thorough review of specification, particularly the cited portions of the specification, the claimed subject matter was found to be insufficiently described to reasonably convey to the skilled artisan that applicant was in possession of the claimed invention at the time of filing. While the specification describes attaching one or more affinity moieties to the primers to permit affinity separation (page 27, lines 12-24), and describes the affinity moiety as being a complementary nucleic acid sequence (page 27, lines 19-24), the specification does not describe the concept of attaching the primers or the affinity moieties to discrete positions on a solid support. From the specification it is clear that the intent of the immobilization on the solid support and the attachment of affinity moieties is to achieve separation of the extended primer from the unincorporated labeled terminators. Page 29, line 31 through page 30, line 3, teach the concept of simultaneous analysis of more than one oligonucleotide using more than one affinity group. This teaching, however, is not equivalent to the attachment of a plurality of oligonucleotide primers or a plurality of affinity moieties to "discrete positions" of a solid support. This concept of "discrete positions" has not been described in the specification and does not appear to have been part of the original inventive concept. The claims, as written, read on methods using oligonucleotide array technology which was not described in the specification. The specification only teaches the general

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concept that multiple oligonucleotide primers each with a different affinity moiety can be used to detect multiple target nucleotides. However, the specification does not teach the more complex concept of specifically arranging the oligonucleotides and/or affinity moieties to discrete positions on a solid support and determining the identity of a target nucleotide by determining its position on a solid support. Claim 63 is particularly unsupported by the specification because the specification contains no description of sorting the extended primers by affinity capture and then determining the identity and location of the terminator to determine the identity of the bases at a plurality of sites. These concepts are unobvious extensions of the teachings that a different affinity moiety can be used to capture a plurality of different primers because the teachings contain no reference using the affinity moieties to sort the primers or to capture the primers at specific locations on a solid support as a means for identification of the target bases. Therefore, for the reasons, given above, the claims introduce new matter into the specification.

5. Claims 60-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 60-63 are indefinite over the recitation of “discrete position” and “defined positions” because these phrases make the claims unclear as to whether each primer or affinity moiety is attached at a specific and unique location on a solid support or whether a discrete position includes a spot in a dot blot, for example, as shown in Figure 8 of the specification, wherein the dot blot contains an entire reaction mixture and not just an individual oligonucleotide primer.

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Claim 64 is indefinite over the recitation of "each different oligonucleotide primer incorporates a corresponding different affinity moiety which permits polymerase extension of the oligonucleotide primer with terminators of a terminator reagent". Firstly, it is unclear as to what is intended to be meant by the "primer incorporates". For example, it is unclear as to whether this refers to the primer incorporating an affinity moiety during the extension reaction or whether this refers to the fact that primer comprises an affinity moiety. This rejection may be overcome by amendment of the claim to recite, for example "each different oligonucleotide primer comprises a corresponding different affinity moiety". Secondly, it is unclear as to what is intended to be meant by the primer permitting polymerase extension. While the specification (page 31) teaches that the presence of the affinity moiety does not affect the 3' extension reaction, the specification does not clarify what is intended to be meant by a primer, per se, permitting polymerase extension.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

September 16, 2002


CARLA J. MYERS
PRIMARY EXAMINER